JUN 10 2005

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AtriCure

510(k) Summary

General Information

Classification	Class II
Trade Name	Isolator™ Transpolar™ pen
Manufacturer	AtriCure, Inc. 6033 Schumacher Park Drive West Chester, OH 45069
Contact	Elsa Abruzzo Vice President, Clinical and Regulatory Affairs

Intended Use

The Isolator™ Transpolar™ pen is a device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Predicate Devices

The predicate device for the Isolator Transpolar Pen are the Medtronic Cardioblate Pen (K013392), the Tissue Link Bipolar Sealer 2.3 (Bipolar Floating Ball) device (K032132) and the AtriCure Bipolar System (K020919).

Device Description

The Isolator Transpolar pen is a sterile, single use, electrosurgery device to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency current.

Materials

All materials used in the manufacture of the Isolator Transpolar Pen are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The Isolator Transpolar Pen is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2008

Atricure, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K050459
Atricure Isolator™ Transpolar™ Pen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: March 11, 2005
Received: March 16, 2005

Dear Mr. Job:

This letter corrects our substantially equivalent letter of June 10, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AtriCure

Indications for Use

510(k) Number (if known): K050459

Device Name: Atricure Isolator™ Transpolar™ pen

Indications For Use:

The Isolator™ Transpolar™ pen is a device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050459